CONFIDENTIAL

A Study To Evaluate The Performance of the Lucira Health All-In-One COVID-19 Test Kit As Compared To The Hologic Panther Fusion SARS-CoV-2 RT-PCR Assay

07A-CLI-006

Version C
October 12, 2020

Protocol Signature Page

By signing this protocol, the Investigator(s) acknowledge and agree:

The protocol contains all necessary details for conducting the study. The Investigators will conduct this study as detailed herein, in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirements and will make every reasonable effort to complete the study within the time designated.

The protocol and all relevant information on the product relating prior clinical experience, which was furnished by the Sponsor (Lucira Health, Inc.), will be made available to all physicians, nurses and other personnel who participate in the conducting of this study. The Investigators will discuss this material with them to assure that they are fully informed regarding the system and the conduct of the study.

This document contains information that is privileged or confidential. As such, it may only be disclosed in accordance with the clinical study agreement or if such disclosure is required by federal or other laws or regulations. Persons to whom any of this information is to be disclosed must first be informed that the information is confidential. These restrictions on disclosure will apply equally to all future information supplied, which is indicated as privileged or confidential.

The Sponsor will have access to any source documentations from which Case Report Form information may have been generated. The Case Report Forms and other data pertinent to this study are the sole property of the Sponsor, which may utilize the data in various ways, such as for submission to government regulatory authorities or in publication of the results of the study.

The conduct and results of this study will be kept confidential. Upon completion of the study, it is the intention of the Sponsor that all Investigators will work collaboratively to prepare a summary publication regarding or describing the study and all the results there from.

Where it is the intention of the Sponsor to file for patent or other intellectual property right protection, publication may be deferred at the opinion of the Sponsor for up to twelve months from the date of completion of the proposed joint publication to allow the Sponsor to make all filings it deems appropriate.

Investigator Details & Signatory:

Protocol Number	Lucira 07A-CLI-006	
Protocol Name	A Study To Evaluate The Performance of the Lucira Health All-In-One COVID-19 Test Kit As Compared To The Hologic Panther Fusion SARS-CoV-2 Assay	
Name (print)	Neeraj Kolla	
Title	PI	
Signature		**Date** 10/13/21

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 ABBREIVIATIONS AND DEFINITIONS

Abbreviation	Description
CFR	Code of Federal Regulations
CRF	Case Report Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed Consent Form
IFU	Instructions For Use
IRB	Institutional Review Board
ISO	International Organization for Standardization
NA	Not Applicable
NAV	Not Available
ND	Not Done
PHI	Protected Health Information
QRI	Quick Reference Instructions
SAE	Serious Adverse Event
UNK	Unknown

Abbreviation/Term	Description
Adverse Event (AE)	Any untoward medical event that occurs to a subject during a study (with onset after first study-specific procedure), whether or not that event is considered study-related
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all the information required by the protocol to be reported to the Sponsor on each study subject
Food and Drug Administration (FDA)	An agency of the US government responsible for promulgating regulations and guidelines that further define how to comply with the Food, Drug and Cosmetics Act of Congress. The FDA is authorized to grant marketing approval to new drugs and devices.
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial subjects are protected
Health Care Professional (HCP)	Person responsible for performing critical study-related procedures
Informed Consent (IC)	A process by which a subject voluntarily confirms his/her willingness to participate in a trial, after having been informed of all aspects of the trial relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
Informed Consent Form (ICF)	The form prepared by the Investigator/Sponsor and approved by the IRB, which must be signed by a subject before entry in a clinical trial. It is the legal written record that the subject, or his/her representative, agrees to voluntarily participate in the investigation.
Institutional Review Board (IRB)	Any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in conformance with 21 CFR Part 56
International Conference on Harmonization (ICH)	A committee consisting of US, EU, and Japanese members organized to develop guidelines for the conduct of clinical studies
Investigator	One or more persons responsible for the practical performance of a trial and for the integrity, health, and welfare of the subjects during the clinical study
Subject	A research participant, also called a human subject or an experiment, trial, or study participant or subject, is a person who participates in human subject research by being the target of observation by researchers

1.1 SYNOPSIS

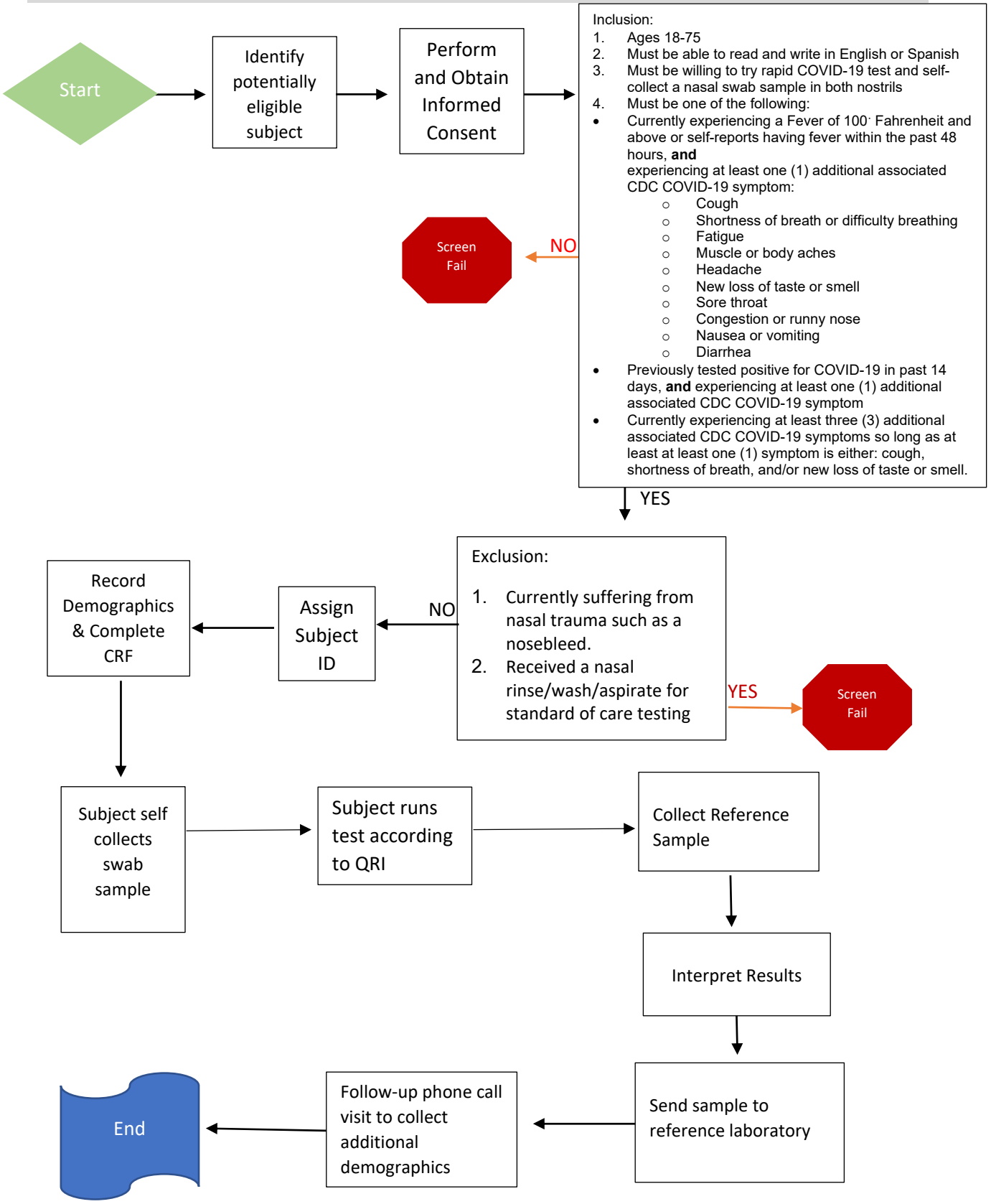
Protocol Title	A Study To Evaluate The Performance of the Lucira COVID-19 All-In-One Test Kit As Compared To The Hologic Panther Fusion SARS-CoV-2 Assay
Protocol Number	07A-CLI-006

Study Description	This Lucira COVID-19 All-In-One Test Kit performance study will be used to establish the performance of the Lucira COVID-19 All-In-One Test Kit as compared to a known high sensitivity RT-PCR molecular assay. The results of this study will be used to demonstrate the Lucira COVID-19 'swab to result in 30 minutes' test kit is similar in performance to known high sensitivity best-in-class molecular assays performed in high complexity labs. The results of this study will be combined with other studies the Sponsor has underway and will support a FDA Emergency Use Authorization (EUA) of the Lucira COVID-19 All-In-One Test Kit. This performance study will include nasal swabs self-collected by study subjects at community-based locations with trained medical staff. After determining subject eligibility and following the completion of the informed consent process, each subject will receive a unique study identification number. A subject's participation in this study will consist of one study visit with one collection event, and one follow-up phone call. The subject self-collects a nasal swab sample according to Lucira COVID-19 Test Kit instructions and runs test according to Quick Reference Instructions (QRI). Subject will be observed during the swabbing collection by the HCP and HCP will document collection details and any collection issues. Nasal swabs obtained from self-collection will be discarded after having been used for testing per QRI. The HCP interprets the Lucira COVID-19 Test results. Following the Lucira COVID-19 All-In-One Test Kit self-collection will be an additional swab collection for reference method testing. One (1) additional NS specimen will be collected either by the health care professional or self-collection, prepared in Transport Medium and sent to the reference laboratory as directed by the Study Operations Manual. Each collection may have a maximum of two swabs, including retests, for a maximum of four swabs per visit. After the initial visit, a follow-up phone call may be conducted to collect additional demographic information for data analysis. Subject's education level, employment status and income will be asked and documented.

Description of Study Intervention/Intended Use	To evaluate the performance of the Lucira COVID-19 All-In-One Test Kit for the qualitative detection of SARS-CoV-2 virus in nasal swab samples as compared to an EUA RT-PCR assay with known high sensitivity among patients who are experiencing COVID-like symptoms. The comparator assay for this study is the Hologic Panther Fusion SARS-CoV-2 RT-PCR Assay.
Objective(s)	Primary Objective: To confirm the Lucira COVID-19 All-In-One test kit provides similar performance to a high complexity lab based molecular diagnostic RT-PCR assay with known high sensitivity. Secondary Objective: To demonstrate the ease-of-use of the Lucira COVID-19 All-In-One Test Kit is suitable for patient/lay user use and does not require a health care professional to run the test.
Study Population	COVID-19 Symptomatic Subjects will be enrolled in the US
Subject Eligibility Criteria	**Inclusion Criteria** 1. Ages 18-75 2. Must be able to read and write in English or Spanish 3. Must be willing to try rapid COVID-19 test and self-collect a nasal swab sample in both nostrils 4. Must be one of the following: • Currently experiencing a Fever of 100· Fahrenheit and above or self-reports having fever within the past 48 hours, **and** experiencing at least one (1) additional associated CDC COVID-19 symptom: ○ Cough ○ Shortness of breath or difficulty breathing ○ Fatigue ○ Muscle or body aches ○ Headache ○ New loss of taste or smell ○ Sore throat ○ Congestion or runny nose ○ Nausea or vomiting ○ Diarrhea • Previously tested positive for COVID-19 in past 14 days, **and** experiencing at least one (1) additional associated CDC COVID-19 symptom • Currently experiencing at least three (3) additional associated CDC COVID-19 symptoms so long as at least at least one (1) symptom is either: cough, shortness of breath, and/or new loss of taste or smell. **Exclusion Criteria** • Currently suffering from nasal trauma such as a nosebleed • Received a nasal rinse/wash/aspirates for standard of care testing

Number of Sites	1 site that will be collecting community-based samples in high prevalence counties in California
Number of Subjects	Up to 110 Subjects
Study Duration	Up to 3 months
Sample Type(s)	Nasal Swab Specimens

1.2 SCHEMA


Start
Identify potentially eligible subject
Perform and Obtain Informed Consent
Inclusion:
1. Ages 18-75
2. Must be able to read and write in English or Spanish
3. Must be willing to try rapid COVID-19 test and self-collect a nasal swab sample in both nostrils
4. Must be one of the following:
• Currently experiencing a Fever of 100· Fahrenheit and above or self-reports having fever within the past 48 hours, and experiencing at least one (1) additional associated CDC COVID-19 symptom:
○ Cough
○ Shortness of breath or difficulty breathing
○ Fatigue
○ Muscle or body aches
○ Headache
○ New loss of taste or smell
○ Sore throat
○ Congestion or runny nose
○ Nausea or vomiting
○ Diarrhea
• Previously tested positive for COVID-19 in past 14 days, and experiencing at least one (1) additional associated CDC COVID-19 symptom
• Currently experiencing at least three (3) additional associated CDC COVID-19 symptoms so long as at least at least one (1) symptom is either: cough, shortness of breath, and/or new loss of taste or smell.
NO
Screen Fail
YES
Exclusion:
1. Currently suffering from nasal trauma such as a nosebleed.
2. Received a nasal rinse/wash/aspirate for standard of care testing
YES
Screen Fail
NO
Assign Subject ID
Record Demographics & Complete CRF
Subject self collects swab sample
Subject runs test according to QRI
Collect Reference Sample
Interpret Results
Send sample to reference laboratory
Follow-up phone call visit to collect additional demographics
End

1.3 SCHEDULE OF ACTIVITIES

Procedure	Screening	Enrollment	Swab Collection	Reference Testing	Follow-up
Identify Potential Subjects	X				
Obtain Written Informed Consent	X				
Review Inclusion/Exclusion Criteria	X				
Assign Subject Number to Eligible Subjects		X			
Record Demographics and Baseline Characteristics		X			
Subject self-collects Nasal Swab Sample and starts test running (test results will be interpreted only by HCP)			X		
Collect Reference Sample			X		
Ship Reference Sample to Reference Lab				X	
Follow-up phone call					X
Adverse Event/Serious Adverse Event Recording		----------X----------			

2 INTRODUCTION

A novel coronavirus, SARS-CoV-2, has caused a worldwide pandemic of respiratory illness, called COVID-19. As of August 2020, the U.S alone has tested over 70 million people for COVID-19[1]. With over 6 million positive cases, 9% prevalence and over 160,000 deaths[1], this highlights the growing importance of obtaining timely results for diagnosis' of COVID-19 to allow for timely treatment, to prevent hospitalization and the development of serious complications, and to positively affect public health by curbing the spread of infection. Rapid diagnostics and point-of-care testing can help detect health conditions to enable earlier self-quarantine and treatment and lower the chances of developing complications or spreading illness.

In preparation for a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) submission, this study is being conducted to allow for the inclusion of more subjects residing in higher COVID-19 prevalence areas than previously completed and/or ongoing clinical studies of the same device. Presently, the Sponsor has a similar study underway in collaboration with Sutter Health in Northern California. However, the combination of wildfires, poor air quality and declining positivity rates (as an indicator of likely disease prevalence) have impeded the ability to rapidly enroll subjects at that site. This protocol seeks to address these enrollment concerns. The information gathered during this study will be combined with other studies the Sponsor has underway and used to help Lucira Health compare the performance of its COVID-19 All-In-One Test Kit to a high sensitivity EUA RT-PCR assay which uses a chemical lysis step followed by solid phase extraction of nucleic acid, consistent with FDA guidance. This study will use the Hologic Panther Fusion SARS-CoV-2 RT-PCR Assay with a nasal swab collection as the reference test or comparator. The Roche Cobas SARS-CoV-2 assay will be used for discrepant testing.

Additionally, this study will confirm it can be used by lay users with or without healthcare professional background or training, as well as that the Quick Reference Instructions are sufficient for lay users to easily run this test.

Known Potential Risks
For this study, the risks to human subjects are minimal. Furthermore, the protocol is exempt from IDE according to §812.2(c) of the IDE regulations because it:

- is noninvasive;
- does not require an invasive sampling procedure that presents significant risk;
- does not by design or intention introduce energy into a subject; and
- is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.

The procedures outlined in this protocol do not involve significant risk to subject safety. Subjects will be provided the Investigator's contact information and will be instructed to notify them of any AEs they experience during or secondary to specimen collection procedures. For all forms of swab collection, there is a minimal risk for visibly bloody swabs.

Known Potential Benefits
There is no direct benefit for a subject's participation.

[1] CDC Testing Data in the U.S., https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html, July 13, 2020

3 INVESTIGATIONAL DEVICE

3.1 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCT

The Lucira COVID-19 All-In-One Test Kit is a rapid, single-use, molecular test for the qualitative detection and discrimination of SARS-CoV-2 viral RNA in nasal swab samples.

3.2 INTENDED USE

The Lucira COVID-19 All-In-One Test Kit is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in nasal swab samples. This test is a single-use test kit that determines whether there is active shedding of the virus which causes COVID-19. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA.

Positive results are indicative of active infection with SARS-CoV-2. Persons who test positive should self-isolate and seek care from their healthcare provider.

Negative results do not preclude SARS-CoV-2 infection. Persons who continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

3.3 PRODUCT LABELING

Product will be labeled according to internal procedures and 21 CFR Part 809.10(c). Investigational material will be labeled minimally with the contents, storage conditions, Lucira Health's name and address and the federal caution statement "For Investigational Use Only. The performance characteristics of the product have not been established."

3.4 STORAGE AND HANDLING

All study supplies should be stored at room temperature. The Investigator site will be responsible for IP accountability.

4 OBJECTIVES

Primary Objective: To confirm the Lucira COVID-19 All-In-One test kit provides similar performance to a high complexity lab molecular diagnostic RT-PCR assay with known high sensitivity. The sensitivity endpoint is 95%.

Secondary Objective: To demonstrate the ease-of-use of the Lucira COVID-19 All-In-One Test Kit is suitable for patient/lay user use and does not require a health care professional to run the test. The endpoint is 95% of subjects are able to start the test running.

5 STUDY DESIGN

5.1 STUDY DESIGN

The study is a prospective, single site study with community-based sampling in high COVID-19 prevalence communities in California. The Investigational device will be tested on-site and the reference samples will be sent to one (1) reference laboratory in the U.S. Testing in the reference laboratory will be performed by trained laboratory personnel. This study, to be performed with medical staff on site, and will include nasal swabs self-collected by study subjects per the QRI. Results from these subjects will be analyzed together with results from other ongoing sponsor studies, as noted on page 10 above.

Community based sampling will be conducted only by trained medical study staff. Study staff will bring all study materials—the Lucira investigational device as well as the reference swab collection kit—to all subjects enrolled in the study. This mobile, outdoor, community-based sampling method will ensure that COVID-symptomatic persons with fever do not travel from their homes, thus risking exposure to others. All medical staff participating in the study will be under the oversight of the study Principal Investigators and wear appropriate PPE during community visits.

A qualified research person will be designated as the Investigator at each site, with the responsibility for oversight of the study in accordance with Good Clinical Practice (GCP) and regulatory requirements. The protocol and subject informed consent will be reviewed by an Institutional Review Board (IRB) and written IRB approval will be issued prior to enrollment of subjects into the study at that site.

A subject's participation in this study will consist of a single visit. Following completion of the informed consent process and a review of Inclusion/Exclusion criteria to determine eligibility, each subject will receive a unique study identification number. Subject demographics including age, sex, race, and ethnicity, will also be collected at this time.

Adult subjects will self-collect a nasal swab sample according to Lucira COVID-19 Test Kit QRI and start the test running according to QRI.

All subjects will be observed during the swabbing collection by the HCP and HCP will document collection details and any collection issues. The HCP will confirm the Lucira COVID-19 Test Kit is running and will interpret the test results once completed. Nasal swabs obtained from self-collection will be discarded after it has been used for testing.

Following the Lucira COVID-19 Test Kit collection will be a collection for reference method testing. A reference swab should not be collected until the Lucira Test Kit is running. The nasal swab reference swab shall be collected in the same manner as the initial collection, prepared in Transport Medium and sent to the Sutter Shared Laboratory as directed by the Study Operations Manual.

To evaluate performance, all reference samples collected will be tested using EUA-cleared molecular method:

- Hologic Panther Fusion SARS-CoV-2 RT-PCR Assay *

Reference testing will characterize specimens as negative or positive for SARS-CoV-2. Therefore, sensitivity and specificity of the Lucira COVID-19 Test will be calculated by comparison with the reference methods.

Additional testing on remaining remnant aliquots may be performed to investigate any discrepant and discordant results as needed, and samples may undergo additional testing by other EUA-cleared molecular methods. The Roche Cobas 6800 SARS-CoV-2 assay will be used for discrepant testing.

If subject consents to storage and future testing of samples, any extra remnants at the end of the study will be returned to the Sponsor for storage.

After the initial visit, a follow-up phone call may be conducted to collect additional demographic information for data analysis. Subject's education level, employment status and income will be asked and documented. Subject may decline to provide the additional information.

*This protocol has been designed to meet FDA Emergency Use Authorization clinical performance requirements for COVID-19 Molecular Diagnostics. The requirements for this study have been reviewed with the FDA and the FDA concurs the Hologic Panther Fusion SARS-CoV-2 assay with a nasal swab collection is a suitable comparator for the Lucira COVID-19 All-In-One Test Kit Investigational Device being studied.

5.1.1 SAMPLE SIZE

The FDA requires a minimum number of 30 positive samples for FDA EUA submission. It is anticipated that up to 110 subjects will be recruited, assuming patients presenting with high chance of being COVID positive are enrolled.

This Lucira COVID-19 test is not intended to give a diagnosis and results of the test will not be available or shared during this visit. Test units may be collected by Lucira after use and may be downloaded for further analysis. All other materials will be discarded. Subjects will be provided their reference test results once available by the Principal Investigator.

Each collection may have a maximum of two swabs, including retests, for a maximum of four swabs per visit.

5.2 SUBJECT DE-IDENTIFICATION

Each subject will be identified with a unique number. All forms and documents related to each subject will be labeled with this unique number. At no time will study paperwork or specimens be marked with a subject's name, any traceable identifier, or Protected Health Information (PHI) except for the ICF, which is signed by the subject. The ICF will be kept separate from the other forms and documents.

5.3 SUBJECT DURATION

The study consists of a single visit. The visit will take approximately 30-45 minutes to compete, and subject participation is complete at the end. There is one follow-up visit in the form of a phone call. Swab collection should take a total of less than ten minutes. Subjects will be provided with the Investigator's contact information and instructed to notify the Investigator if they experience any complications from specimen collection procedures.

Subjects are free to withdraw consent and discontinue participation in the study at any time. A subject's participation in the study may be discontinued at any time at the discretion of the study supply. The following may be justifiable reasons for the study staff to remove a subject from the study:

1. The subject was erroneously included in the study or was found to have an exclusion criterion.
2. The subject is uncooperative or unable to complete the required study tasks
3. The subject experiences an Adverse Event (AE)/Serious Adverse Event (SAE) during the specimen collection procedure that is considered intolerable by subject or Investigator.

To the extent possible, safety data will be collected on subjects who discontinue participation in the study due to safety reasons.

6 STUDY POPULATION

6.1 INCLUSION CRITERIA

The study population will include males and females ages 18 and older, currently exhibiting COVID-19 like illness as defined in this study protocol who meet the criteria defined in criteria below:

1. Ages 18-75
2. Must be able to read and write in English or Spanish
3. Must be willing to try rapid COVID-19 test and self-collect a nasal swab sample in both nostrils
4. Must be one of the following:
   - Currently experiencing a Fever of 100· Fahrenheit and above or self-reports having fever within the past 48 hours, **and**
     experiencing at least one (1) additional associated CDC COVID-19 symptom:
     - Cough
     - Shortness of breath or difficulty breathing
     - Fatigue
     - Muscle or body aches
     - Headache
     - New loss of taste or smell
     - Sore throat
     - Congestion or runny nose
     - Nausea or vomiting
     - Diarrhea
   - Previously tested positive for COVID-19 in past 14 days, **and** experiencing at least one (1) additional associated CDC COVID-19 symptom
   - Currently experiencing at least three (3) additional associated CDC COVID-19 symptoms so long as at least at least one (1) symptom is either: cough, shortness of breath, and/or new loss of taste or smell.

6.2 EXCLUSION CRITERIA

A subject is excluded from participating if they are:

1. Currently suffering from nasal trauma such as a nosebleed
2. Received a nasal rinse/wash/aspirates for standard of care testing

6.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Target Subject Population

A mix of:

- Symptomatic COVID-19 Subjects
- Subject gender and age
- English and Spanish speaking subjects

Recruitment Methods

Recruitment will consist of subjects who are suspected to be COVID-19 positive. Social media and outreach will be used to recruit subjects who are experiencing COVID-like symptoms. Subjects will be directed to a webform where they will receive follow up telephone screening and scheduling.

6.4 SUBJECT COMPLETION, DISCONTINUATION AND WITHDRAWAL

6.4.1 SUBJECT COMPLETION

Subject's participation is complete after sampling procedures. There is one follow-up visit in the form of a phone call to attempt to collect additional demographic information. Subjects will be provided with the Investigator's contact information and will be instructed to notify the Investigator if they experience any complications from the specimen collection procedures. Subjects will receive notification of their reference test results according to Principal Investigator's standard of care practices.

6.4.2 SUBJECT DISCONTINUATION AND WITHDRAWL

Subjects are free to withdraw consent and discontinue participation in the study at any time. A subject's participation in the study may also be discontinued at any time at the discretion of the Principal Investigator. The following may be justifiable reasons for the Investigator to remove a subject from the study:

- The subject was erroneously included in the study or was found to have an exclusion criterion.
- The subject is uncooperative (i.e. not providing swabs specimens for this research).
- The subject experiences an Adverse Event (AE)/Serious Adverse Event (SAE) during the specimen collection procedure that is considered intolerable by subject or Investigator.

If a subject decides to discontinue participation in the study, information about the reason(s) for discontinuation and recording of any potential AEs should be documented. The Investigator will provide information describing the reason for discontinuation. The Investigator will attempt to follow all AEs until resolution.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 MATERIALS

7.1.1 MATERIALS PROVIDED BY SPONSOR

- Lucira COVID-19 All-In-One Test Kit which includes: 2 AA batteries, Test Unit, Sample Vial, Nasal Swab and Quick Reference Instructions (QRI)
- Bleach wipes
- Mirror
- Reference Swab Collection Kit including: Nasal swab and 2.5 ml Transport Medium of 0.85% Saline
- Refrigerated shipping containers and shipping supplies
- External Run Controls (if required)
- Gift Cards (compensation)

Each subject will be given a Test Kit provided by the Sponsor. The Investigator or designee is responsible for maintaining accountability records for all inventory transactions (i.e. receipt, utilization, and return). The investigational product may only be used in accordance with this approved protocol and must not be used for any other purpose. Investigational product may only be used for subjects who have provided written informed consent to participate in this study and meet all inclusion/exclusion criteria.

An Accountability Form details the quantity and description of the investigational product, the shipment of investigational material, and clinical supplies from the Sponsor or its representative to the

Investigator. The Investigator must ensure that the investigational product is maintained at the prescribed environmental conditions in a controlled location with limited access, as directed in the Study Operations Manual.

The Investigator or designee must complete an Accountability Form upon completion or termination of the study. All unused study materials, after device accountability, together with a copy of the Accountability Form, will be returned to the Sponsor or its representative. A copy of all Accountability forms should be retained in the site files.

7.1.2 MATERIALS PROVIDED BY THE SITE

- Shipping materials for shipping the reference swabs to the reference laboratory.

7.2 SCREENING AND ENROLLMENT

7.2.1 IDENTIFY POTENTIAL SUBJECTS WITH COVID-19 SYMPTOMS

The potential subject will be asked to provide relevant medical history information regarding COVID-19 like symptoms, which will be evaluated against all inclusion and exclusion criteria. At the time of the study visit, the subject must be currently experiencing a fever of 100 degrees Fahrenheit or self-reports having fever within the past 48 hours or have previously tested positive for COVID-19 in the past 14 days **and** at least one additional associated CDC COVID-19 symptom such as Cough, Shortness of breath or difficulty breathing, Fatigue, Muscle or body aches, Headache, New loss of taste or smell, Sore throat, Congestion or runny nose, Nausea or vomiting, Diarrhea, or Currently experiencing at least three (3) additional associated CDC COVID-19 symptoms so long as at least at least one (1) symptom is either cough, shortness of breath, and/or new loss of taste or smell.

To be eligible for this study, subject must also be willing to try rapid COVID-19 test and self-collect a nasal swab sample in both nostrils. Preliminary assessment of the subject by the Investigator/designee should be suggestive of COVID-19 based upon his/her medical judgment.

7.2.2 OBTAIN WRITTEN INFORMED CONSENT

All potential study participants must be given time to review the consent form, have their questions answered to their satisfaction, and sign the IRB-approved informed consent prior to performing any study procedures. The informed consent process, including the date and time of signature, will be recorded on the source document to confirm that no study procedures were performed prior to obtaining the subject's consent. Subjects will be given a copy of the informed consent form.

7.2.3 REVIEW INCLUSION/EXCLUSION CRITERIA

The Investigator and/or designee should review all criteria to determine if the subject is eligible for enrollment. Eligibility will be documented in the source document and CRF.

7.2.4 PRIOR AND CONCOMITANT MEDICATIONS AND THERAPIES

No subject should be denied necessary treatment because of being a participant in this study.

7.2.5 ASSIGN SUBJECT NUMBER TO ELIGIBLE SUBJECTS

See the section of the protocol entitled "Subject De-Identification".

7.2.6 RECORD DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographic data including age, sex, race, and ethnicity (Hispanic or Non-Hispanic) will be documented and recorded during initial study visit. A follow-up phone call will be conducted after to attempt to collect additional demographic information including subject education level, employment status and income.

7.2.7 RECORD RELEVANT MEDICAL/MEDICATION HISTORY

The subject will be asked to provide information regarding COVID-19 symptoms they are currently experiencing at the time of the study visit. Relevant signs, symptoms and medication information will be documented in detail in the source document.

7.3 PROCEDURE

The Lucira COVID-19 All-In-One Test Kit will be performed before reference test specimen collection at the clinical site. A Healthcare provider will provide each subject with a Lucira COVID-19 All-In-One Test Unit. Subjects will be asked to read the Quick Reference Instructions (QRI)

Subject will then be instructed to begin the Lucira test on their own according to the QRI.

This will involve a nasal self-collection and running the test. Only the HCP will interpret the test result.

The HCP will document all observations during the subject self-collection. Subjects will be asked to complete a short questionnaire to assess ease of self-collection and instructions clarity.

After the Lucira COVID-19 Test Kit is running, the reference nasal swab will be collected either by the subject or the HCP. The HCP will document collection details.

7.3.1 QUALITY CONTROL PROCEDURES

The Lucira COVID-19 Test Kit does not require an external control be performed. However, as this is a study for FDA EUA submission, Lucira recommends that daily controls be performed to monitor for any study anomalies. Lucira recommends the ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (0.5ml). A recommended procedure for running the ZeptoMetrix External Run Controls will be provided in the Study Operation Manual.

7.3.2 TESTING PROCEDURE

- Subject Self-Collection and Specimen Testing

The Lucira nasal swab self-collection will be obtained before the reference test sample is collected. Subjects will be provided with the Lucira COVID-19 Test Kit and collect one (1) nasal swab according to the QRI and test the sample on the Lucira COVID-19 All-In-One Test. HCP will observe subject during this process and document any observations and deviations from the QRI.

If a swab is contaminated or the test is invalid, subjects will be asked to collect a new sample and test the sample on a new device. The date and time of collection will be documented. Contaminated swabs (e.g. dropped) should be discarded. At the research staff's discretion, one additional attempt may be made to collect a clean swab.

- Reference Nasal Swab (NS) Collection

One NS for reference testing will be obtained from each subject who completes the self-collection step specified in the QRI and runs the Lucira COVID-19 All-In-One Test regardless of result. Subjects

who do not successfully complete self-collection specimen testing will not be required to provide the reference collection. The reference collection may be self-collected or HCP collected.

If a swab is contaminated or the test is invalid, subjects will be asked to collect a new sample and test the sample on a new device. The date and time of collection will be documented. Contaminated swabs (e.g. dropped) should be discarded. At the research staff's discretion, one additional attempt may be made to collect a clean swab.

7.3.3 OBSERVATIONS AND QUESTIONNAIRES

- Self-Collection Observations

While subject is performing the Lucira COVID-19 All-In-One Test, the HCP will complete the observational CRF documenting collection details.

- User Experience Questionnaire

Subjects will complete the User Experience Questionnaire after self-collection and testing procedures to ask about their experience with collecting a sample, running the test, and their overall perception of the product.

7.3.4 ADVERSE EVENT RECORDING

See the section of the protocol entitled "Risks and Adverse Events"

7.3.5 COMPENSATION

Subjects will be compensated for their visit time and inconvenience. Subjects who are disqualified during the study or are unable to complete the research through no fault of their own will still receive compensation. Compensation amount of $150.00 will be given in a form of a Gift card and provided to the site by the sponsor. Proper handling of compensation requires site to document individual subject compensation in subject CRF and track in site Compensation log.

7.3.6 DISPOSAL OF USED TEST UNITS

At the discretion of the Sponsor, all used Test Units may be collected and returned to sponsor for download of internal data and proper destruction of unit. Site to follow Study Operation Manual for labeling and shipping of used test units.

7.3.7 REFERENCE METHOD AND ADDITIONAL TESTING METHODS

Nasal swab samples are important as they provide a natural nasal matrix to conduct analytical reference testing and research. It is imperative that specimens obtained for reference testing are prepared and shipped to the reference laboratory as directed by the Study Operations Manual following collection.

Specimens will be shipped daily to the reference laboratory and will be stored refrigerated at each clinical site until the shipment is made. Specimens shipped from the site to the reference laboratory must not be frozen prior to shipment and must be shipped within 48 hours of collection. Site staff will receive training from the Sponsor or its representative on procedures required to process specimens for shipment to the reference laboratory. Specimens will be de-identified and shipped with ice packs to maintain the required temperature (2-8°C). Reference laboratory requisitions will be filled out clearly and completely and must accompany the specimens to ensure correct testing is performed on the specimens. Inadequate documentation could result in a delay in testing and possible specimen rejection.

Upon receipt, the reference laboratory will verify the contents of each shipment and communicate any missing or damaged contents to the Sponsor. Next, the Transport Medium required for reference testing will be removed from the Transport Medium tube, and the remnant specimen will be aliquoted, labeled, and stored or returned to sponsor if subject agrees to consent of storage of samples. Aliquots will be stored for future testing to be performed both during and after the study. All results will be communicated to the Sponsor or its representative. Reference test results will be entered into a database and compared with the corresponding Lucira COVID-19 All-In-One Test results.

Additional testing for discrepant results may be performed to investigate the discrepancy. The discrepant sample, along with some or all non-discrepant samples, may undergo additional testing.

Subjects who agree to allow their specimens to be stored indefinitely with Lucira Health may be used for future research. The stored specimens will not be identified by name or any personal identification, but by an assigned code (de-identified).

At the end of the study, at Sponsor's discretion, all residual remnant aliquots remaining at the reference laboratory or additional testing laboratories will be sent to the Sponsor or its representative or destroyed.

IATA Dangerous Goods Regulations (60th edition) and any applicable local, state, and federal regulations for transport of dangerous goods and biological specimens will be followed for all shipments.

7.4 RISKS AND ADVERSE EVENTS

No side effects or adverse effects are anticipated in this study. However, events that may be related to the specimen collection procedure, but result only in local, mild, and transient discomforts include (a) local, mild discomfort or "tickling sensation" in the nose, (b) sneezing, (c) slight gagging or mild irritation in the nose, (d) eye tearing or (e) minor/temporary nosebleed. These risks will not be considered AEs for this study but will be recorded in source documentation.

AEs experienced by the site staff conducting the study will include any unintended direct contact or bodily exposure to biological fluids or specimens while performing protocol related testing. Personnel performing the test will also be instructed to report any AEs that happen to them during testing.

The investigator and designated study personnel will monitor each subject for AEs during the study. AEs reported between consent and completion will be recorded in the Adverse Event Reporting Form. All AEs reported will be tabulated and reviewed during the study in accordance with the procedure for reporting AEs and SAEs.

Follow-up of AEs will occur in accordance with each individual case. Subjects will be reimbursed for any further medical costs from any treatments or tests that arise because of an adverse event directly related to this study. All AEs reported will be tabulated and reviewed during the study in accordance with Sponsor's or its representative's internal procedures and 21 CFR 812.150 and 21 CFR 812.46.

The date and time of onset of any AE or SAE experienced by a subject after signing the informed consent form and assent form, if applicable, until twenty-four (24) hours following study completion or termination (if self-reported by the subject) will be recorded on the source document. The Investigator and/or designee will continue to monitor the subject with additional assessments until the event is

considered resolved, stabilized, or is lost to follow-up. The date of resolution will also be recorded on the source document.

The full description of any AE or SAE, including the nature, date and time of onset and resolution, determination of seriousness, frequency, severity, treatment, outcome, and relationship to the study will be recorded on the Adverse Event & Serious Adverse Event Report Form.

SAEs must be reported to Lucira Health or its representative within 24 hours of the Investigator's first knowledge of the event. A completed SAE report and supporting documentation, using the form entitled "Unanticipated Event" form, must be completed and transcribed into the EDC system within 24 hours of Investigator's first knowledge. Within this same timeframe, an email documenting knowledge of a potential SAE must be sent to Grace Gonzaga, Clinical Trials Manager, at: grace@lucirahealth.com.

A serious adverse event (SAE) is defined as any adverse event that results in any of the following outcomes:

- Death
- Life-threatening experience
- Required or prolonged inpatient hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly
- Important medical events that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above

Regulatory Reporting Requirements for Adverse Events

The Sponsor is responsible for submitting reports of Unanticipated Adverse Device-Related events to the FDA within 10 working days of the Sponsor first becoming aware of the event, and follow-ups as requested by the FDA.

IRB Reporting Requirements for Adverse Events

If a subject experiences an Unanticipated Adverse Device Effect (UADE) because of this study, the Investigator must submit an Adverse Event Form, as per the instructions on the form, to the Sponsor within 24 hours, and the IRB within the time specified by the IRB. Incidents and deviations relating to subject safety and informed consent will also be reported to the Monitor and as required to the IRB. All other AEs must be notified to the Monitor within 24 hours, and the Monitor will then notify the Sponsor. The Monitor will submit to the IRB per the IRB guidelines.

8 DATA ANALYSIS AND STATISTICAL CONSIDERATIONS

8.1 SAMPLE SIZE

Up to 250 subjects will be recruited for this study to provide at a minimum 30 natural positive clinical specimens collected from patients suspected of SARS-CoV-2 infection and a minimum of 30 individual negative samples.

8.2 SELECTION OF SUBJECTS AND DATA EXCLUSION

The number of patients enrolled in the study, how they were recruited, number withdrawn, and reasons for withdrawal will be summarized.

- Demographics: Subject demographic data will be summarized with descriptive statistics for the entire study population and by SARS-CoV-2 diagnosis result (positive or negative for each). Demographic variables will include:
  - Sex
  - Age (years) as a continuous measure and categorized (N, %) by the following age groups:
    - 18 – 29 years
    - 30 – 44 years
    - 45 – 60 years
    - ≥ 65 years
    - Unknown
- Race categorized as: American Indian/Alaska Native, Asian, African American/Black, Caucasian/White, Native Hawaiian/Pacific Islander, Other, Unknown, or Refused.
- Ethnicity categorized as: Hispanic or Latino, Not Hispanic or Latino, Other, Unknown, or Refused.
- Language: English or Spanish
- Education Level
- Employment status
- Income

A cross-reference of sex by age group may be presented.

8.3 DATA ANALYSIS

All summaries and analyses will be presented in tabular or graphical form. "Descriptive Statistics" refers to mean, median, standard deviation (SD), minimum and maximum for continuous measurements, and number and percentage of patients in each level of a categorical measurement. All statistical tests will be 2-tailed and performed at the 5% significance level, unless stated otherwise.

- Lucira COVID-19 All-In-One Test and Reference Test Result Accountability
  The number and proportion of valid and invalid test results will be presented overall and by site. Non-evaluable samples will be excluded from the analyses.

- Analysis Sets
  There will only be one analysis set consisting of samples with valid Lucira COVID-19 All-In-One Test results and valid reference results. However, testing of samples by one or more additional EUA-cleared tests as described in the Study Design and further analysis of any discrepant results may result in additional analysis sets to determine the performance of the Lucira COVID-19 Test. Valid Lucira COVID-19 Test results may be positive or negative for COVID-19.

  For all invalid Lucira COVID-19 All-In-One Test results, one additional specimen collection should be attempted, and the Lucira COVID-19 Test should immediately be re-run with a new Test Unit and new Sample Vial. If specimen recollection leads to a valid Lucira COVID-19 Test result, that valid retest result should be reported. If the original Lucira COVID-19 Test result displays, "Invalid", then this test result shall be considered completely invalid and therefore non-evaluable.

- COVID-19 Prevalence Rate / Expected Values
  Study prevalence of SARS-CoV-2 will be summarized by counts and percentages:
  - 18 – 29 years
  - 30 – 44 years
  - 45 – 64 years
  - ≥ 65 years

- 18-≥ 65 years
- All ages

➢ Collection Performance/ Incidence Rate
Study observations will be summarized by counts and percentages:
- Self-Collection, Self-tested
- User Experience

➢ Missing Values
Missing values will not be imputed for any of the study assessments.

➢ Data Exclusions
The following will result in subjects being removed from final data analysis:
- Subject withdrawals
- Subject does not meet inclusion/exclusion criteria
- Swab specimens were not processed according to protocol
- Missing results
- Excluded by an Event

This analysis will be presented across all study sites and by individual study site.

➢ Efficacy Analysis
Sensitivity and specificity along with their associated 2-sided Wilson Score 95% Confidence Intervals will be estimated for SARS-CoV-2, on the Lucira COVID-19 All-In-One Test in comparison to the reference test using the formulas below and a 2 x 2 contingency table (Table 13.1). If banked, prospectively collected sources or retrospective/archived specimens are accessed to provide sufficient numbers of positive SARS-CoV-2 results, then sensitivity and specificity will be estimated along with their 2-sided Wilson Score 95% Confidence intervals for SARS-CoV-2 in the banked/retrospective/archived population separately from the estimates in the prospectively collected sample population.

Positive Percent Agreement: a/(a+c) x 100

Negative Percent Agreement: d/(b+d) x 100

Table 13.1: 2 x 2 table for calculation of sensitivity and specificity:

	Reference *(Professional Swab)*		
	Positive	Negative	Row Totals
Lucira Positive	a	b	
Lucira Negative	c	d	
Column Totals			

- Invalid Rate

The invalid rates, along with their associated 2-sided Wilson Score 95% Confidence Intervals will be estimated for SARS-CoV-2 on the Lucira COVID-19 All-In-One Test.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

Upon receiving IRB approval, the Investigator must receive IRB-approved informed consent and the letter from the IRB granting approval. The letter(s) must clearly state the version of the protocol and the informed consent that they have approved as well as any other documents, such as advertisements or other materials, they may have reviewed and approved.

Before recruitment and enrollment into the study, each prospective candidate will be given a full explanation of the nature and purposes of the study and a copy of the IRB-approved informed consent form to review in English or Spanish. Once the essential study information has been provided and the Investigator is assured that each individual volunteer understands the implications of participating in the study, the subject will be asked to give consent to participate in the study by signing the informed consent form. The consent forms shall be signed and dated by the appropriate parties.

The informed consent process, including the date and time of signature, will be recorded on the consent form to confirm that no study procedures were performed prior to obtaining the subject's consent. A subject will be given a copy of the signed informed consent form.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

If Lucira Health or its representative, the Investigator, or any national regulatory officials discover conditions during the study that indicate that the study, site or intended use operator should be terminated, this action may be taken after appropriate consultation between Lucira Health, its representative, and the Investigator. The study may be terminated prematurely by the Principal Investigator or his/her designee and Lucira Health if:

- The number and/or severity of AEs justifies termination of the study
- The discovery of an unexpected, serious, or unacceptable risk to enrolled subjects
- New data becomes available which raise concern about the safety of the study device, such that continuation might cause unacceptable risk to subjects
- The study may be terminated at an individual site and another site sought if there is a failure to recruit enough subjects for the study
- The decision on the part of Lucira Health to suspend or discontinue testing, evaluation, or development of the study device
- Failure of the Investigator to comply with pertinent regulations
- Submission of knowingly false information from the research facility to Lucira Health, Monitor or any regulatory officials
- Insufficient adherence to protocol requirements

In addition, the Sponsor reserves the right to discontinue the study, but intend only to exercise this right for valid scientific or administrative reasons.

After such a decision, written notification must be sent to the IRB along with any IRB-required filings. Study termination and follow-up will be performed in compliance with the conditions set forth in GCP requirements.

9.1.3 CONFIDENTIALITY AND PRIVACY

Confidentiality

During the enrollment process, each subject will be given a unique identifier to ensure anonymity. All study-related materials, specimens, documents, and data held by the Sponsor will refer to the subject's unique subject ID. Any data that may be published in internal reports, abstracts, scientific journals, or presented at medical meetings will reference a unique subject code and will not reveal the subject's identity. At no time should any data forms or specimens be marked with the subject's name or any other traceable identifier. The informed consent form (ICF), which contains the subject's name, will be kept separately at Lucira Health in a secure locked location. At no time will the original or a copy of the ICF revealing the subject's name be distributed outside of the Lucira Health research team.

Disclosure of Data

All information obtained during the conduct of this study will be regarded as confidential and written permission from Lucira Health is required prior to disclosing any information relative to this study.

Data Access

The Investigator and the Investigators' designated staff personnel will have access to the following subject data: Name or Initial, and previous research record.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator.

9.1.4 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator
Neeraj Kochhar, MD
Neeraj Kochhar MD Family Medicine
15195 National Avenue Suite 205 Los Gatos, CA 95032
408-829-3033
drneerajkochhar@gmail.com

9.1.5 CLINICAL MONITORING

The task of the study monitor is to ensure the acceptable conduct of the study through frequent contacts by phone, email, and in person with the responsible Investigator, in accordance with the Sponsor's or its representative's internal procedures. The Sponsor or its representative is responsible for the organization, monitoring supply of study materials, and quality assurance for the clinical study. Details of monitoring will be described in the monitoring plan.

Prior to the start of this study, Lucira Health will initiate each site to discuss the protocol, roles and responsibilities, data management and regulatory requirements. During the study, Lucira Health will monitor study progress in accordance with the protocol and applicable regulations. Lucira Health personnel or designee may perform an audit at any time during or after completion of the study, and all data pertaining to a subject's participation and all study-related documentation in this investigation must be made available. In addition, a representative from a regulatory authority may choose to inspect a study site at any time prior to, or after completion of the clinical study. All pertinent study data should be made available to the regulatory authority for verification, audit, or inspection purposes.

When the enrollment goal is reached, Lucira Health or its representative will notify the sites the study is complete.

The duration of the study is expected to be approximately 3 months. When the study is ready to be terminated, a Site Closeout will be conducted. All unused investigational materials will be returned to Lucira Health or its representative at that time. Study documents will be checked for completeness and filed. The Investigator will allow Lucira Health and/or its representative and/or any regulatory authority to inspect all CRFs and study-related documents to verify the study was performed according to protocol. Monitors will review for completeness all informed consent forms as well as verify source documentation per the monitoring plan.

To ensure the accuracy of data, direct access to source data by the Sponsor, its representative, and regulatory authorities is mandatory. Direct access to source data may be required to perform de-identified analysis both during or after the study. The Sponsor reserves the right to terminate the study for refusal of the Investigator/Institution to supply source documentation of work performed in the study.

The following are source data for this study:

- Source Documents
- Informed Consent Forms

9.1.6 QUALITY ASSURANCE AND QUALITY CONTROL

Lucira Health is responsible for the training, organization, monitoring supply of study materials, and quality assurance for the clinical study. Prior to the start of this study all study staff will be trained on the protocol, roles and responsibilities, data management and regulatory requirements. Details of clinical monitoring will be described in the Study Operation Manual.

The study will be reviewed by Lucira Health or its representative to monitor study progress in accordance with the protocol and applicable regulations and ensure validity and completeness of informed consents and applicable documents. Furthermore, Lucira Health personnel or designee may perform an audit at any time during or after completion of the study. All pertinent study data should be made available for verification, audit, or inspection purposes.

9.1.7 DATA HANDLING AND RECORD KEEPING

9.1.7.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data gathered during the study visit will be recorded on the source document and CRFs provided by Lucira Health. Data collection is the responsibility of the clinical trial staff at the site under the

supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The following are acceptable abbreviations for missing data points:

ND	Not done
UNK	Unknown
NA	Not applicable
NAV	Not available

All entries must be in permanent, black or blue ink. So an error remains legible, it will have a single line drawn through it with the correct data, recorder's initials and date of correction entered beside it. Erasing or obliterating errors, including the use of correction fluid, e.g. "white out", is prohibited unless it involves protected health information of a subject.

9.1.7.2 STUDY RECORDS RETENTION

Essential documents are those documents, which individually and collectively, permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, Lucira Health and its representative with the standards of GCP and with all applicable regulatory requirements. The Investigator is responsible for compliance with GCPs and completion/updating of all required regulatory documentation (e.g. Investigator agreement, Financial Disclosure, CVs from personnel listed on Investigator Agreement, etc.). In particular, the Investigator will ensure Lucira Health or its representative is provided with financial disclosure information, including staffing changes and changes to financial arrangements, which will be updated during the course of the study, at site closure/database lock and for 1 year following completion of the study. The Investigator or designee will also maintain and provide an Authorized Study Personnel Log and protocol deviation forms to Lucira Health or its representative and to the IRB.

US Federal law codified in 21 CFR section 812, requires a copy of all records (source documents, data forms, test article disbursement records, etc.) that support this study must be retained in the files of the responsible Investigator for a minimum of two years following US regulatory clearance or approval for the claim investigated. The Sponsor will retain records for a minimum of 5 years after the termination of the study. If no FDA application is filed, the Sponsor will retain records for a minimum of 7 years (25 years in Canada) after the product is no longer sold or as agreed upon with the Sponsor or its representative.

9.1.8 PROTOCOL DEVIATIONS

No changes in protocol execution, except to eliminate an immediate hazard, shall be affected without the mutual agreement of the Investigator and Lucira Health. It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 2 working days of identification of the protocol deviation, or within 2 working days of the scheduled protocol-required activity.

Clinical study events will be reported using an Event Report Form and follow-up will take place accordingly. Deviations that affect subject safety will be reported to the IRB. Deviations and any incidents or queries that result in data exclusion will be reported in the final report.

9.1.9 PUBLICATION POLICY

The publication policy is detailed in the Clinical Trial Agreement for this study. All information obtained during the conduct of this study will be regarded as confidential, and written permission from Lucira Health is required prior to disclosing any information relative to this study. Only summary manuscripts prepared for publication by Lucira Health in accordance with the policy established and previously presented to the Investigator by Lucira Health will be permitted. This requirement should not be construed as a means of restricting publication; it is intended to assure concurrence regarding data, evaluations, and conclusions, and also to provide an opportunity to share with the Investigator any new and/or unpublished information of which he/she may be unaware.

9.1.10 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

9.2 PROTOCOL AMENDMENTS

The protocol may be amended during the study. Changes that affect the study population or conduct of the study will be described in detail in the Clinical Study Report.

Neither the Investigator nor the Sponsor will amend the Protocol without first obtaining the approval of the amendment in writing by the IRB. No changes in protocol execution, except to eliminate an immediate hazard, shall be affected without the agreement of the Investigator and Lucira Health. All changes must be documented by signed protocol amendments and submitted to the IRB.

Protocol amendments will be approved by the IRB, including changes to the Informed Consent Form. It should be noted that where an amendment to the Protocol substantially alters the study design or the potential risks to subjects, each subject's consent to continue participation should be obtained.

Once the final protocol has been issued and signed by the Investigator and the Sponsor, it shall not be formally altered. Protocol amendments are alterations to a legal document and have the same legal status. Therefore, they must pass through appropriate steps before being implemented. In general, any important change that theoretically increases risk to subjects constitutes an amendment.

It is the responsibility of the Sponsor or its representative to submit the amendment to the IRB for their approval; written approval should be obtained, and a copy provided to the Sponsor or its representative.

The original signed copy and amendments will be kept in the Sponsor Regulatory Binder unless requested by the Investigator or the IRB.

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale.

Version	Date	Description of Change	Brief Rationale
vB	18SEP2020	Inclusion & exclusion criteria updated to include Spanish speaking subjects, subjects previously tested positive within 14 days, and subjects experiencing multiple symptoms	To optimize recruitment efforts
vC	12OCT2020	Study procedures updated to include follow-up phone call to collect additional subject demographic information	To include in data analysis

END DOCUMENT